Office of Inspector General Report on State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs: Summary and Impact to ASHP

Prepared by ASHP's Government Affairs Division

The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) has released their long awaited report on State interaction with the HRSA 340B program (State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs).[1] Below is a summary of the findings, recommendations, and impact on ASHP and its members.

As background, a 2005 Federal lawsuit alleged that covered entities overcharged Medicaid for drugs purchased under the 340B program. As a result, Senator Charles Grassley (R-IA) requested that OIG investigate the claims and describe State Medicaid reimbursement practices related to the 340B program. To comply with this request, the OIG surveyed all 50 States plus the District of Columbia Medicaid programs[2], receiving a 100% response to their inquiry.

Summary of the OIG's Findings

1. Twenty-six States have written 340B policies that direct covered entities to bill Medicaid at cost for 340B-purchased drugs.
   - All but one of these States direct covered entities to bill at average acquisition cost (AAC) for 340B-purchased drugs[3]; the remaining State's written policy reimburses 340B-purchased drugs at rates based on average wholesale price (AWP) minus a certain percentage.
   - The other twenty-five States do not have written 340B policies and rely on HRSA's 1993 guidance directing covered entities to bill States at AAC, however;
     - Subsequent HRSA guidance directs covered entities to refer to States' policies, which may cause confusion about jurisdiction over guidance at the rate at which to bill.

[1] OEI-05-09-00321, June 2011

[2] The term "States" in the context of this summary includes the fifty States and the District of Columbia.

[3] Of the 25 States reimbursing at AAC, seven have a dispensing fee for 340B drugs that is higher than for non-340B drugs to encourage their use for the Medicaid population.

2. States do not have necessary pricing information to create prepay edits for 340B-purchased drugs;
    - States do not have access to AAC or 340B ceiling prices because of logistical and legal issues, nor can they create effective prepay edits without AAC or 340B ceiling price information
        - 340B ceiling prices are calculated using average manufacturer price (AMP) of which States do not have access.
        - Although States expect covered entities to bill at AAC, no State reported collecting AAC data from covered entities.
    - Twenty States conduct retrospective reviews to identify overpayments for 340B-purchased drugs either through monitoring or audits.
3. Fourteen States use only the Medicaid Exclusion File to identify 340B claims.
4. Over half of States developed alternatives to the Medicaid Exclusion File to identify 340B claims and prevent duplicate discounts.
    - Thirty States reported that they developed alternatives to the Medicaid Exclusion File to identify 340B claims and prevent duplicate discounts.
        - Twenty-six of the thirty States contacted all or some of the covered entities in their States directly and created their own lists of covered entities that dispense 340B drugs to Medicaid patients.
        - Nine of the thirty States instruct covered entities to identify specific 340B claims using the National Council for Prescription Drug Plan (NCPDP) Telecommunication Standard when submitting a 340B claim.
        - Two States instruct covered entities to bill using an alternative billing identification number.
        - Ten of the thirty States that use alternatives reported that they do so because of inaccuracies in the Medicaid Exclusion File.
5. Seven States reported that they do not use any method to identify 340B claims.

<u>Recommendations</u>

The OIG recommends that:

1. CMS direct States to create written 340B policies.
2. CMS should inform States that they can have covered entities use the NCPDP Telecommunication Standard to identify 340B claims.

3. HRSA should seek legislative change to allow the agency to share 340B ceiling prices with States to help them create prepay edits to oversee their reimbursements for 340B-purchased drugs.[4]
4. HRSA should instruct covered entities to update their information in the Medicaid Exclusion File to ensure that covered entities' information in the file is correct.

Impact on ASHP and its Members

- There is a lack of uniformity and standardization in how States administer and enforce the 340B program, potentially resulting in overpayments or duplicate discounts for 340B-covered drugs.
- The lack of transparency in pricing and billing may create confusion for health-system pharmacists as they interact or seek guidance from their State Medicaid agencies.
- As States seek to modify administration of the 340B program, careful attention will need to be paid with regard to how the States monitor and enforce the program at the covered entity level.

Next Steps

- ASHP's Government Affairs Division will identify further issues for discussion with HRSA on the OIG's recommendations in this report.
- Members are encouraged to contact their Section Director or ASHP point-of-contact regarding direct and indirect experience with State Medicaid agencies and their policies, both written and unwritten, regarding the 340B program.
- For general inquiries about the 340B program or the OIG report please contact Christopher Topoleski, Director of Federal Regulatory Affairs at 301-664-8692 or via e-mail at ctopoleski@ashp.org.

[4] The ACA gave HRSA authority to share 340B ceiling prices with covered entities. However, this authority does not extend to sharing these prices with the States and the agency have to seek further legislative authority to share 340B ceiling prices with States.